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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,785	10/27/2003	Egisto Boschetti	9676-314-999	1038
20583	7550	09/04/2008		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER JONES, DAMERON LIVEST	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			09/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/692,785

Applicant(s)

BOSCHETTI, EGISTO

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/27/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-11, 15-21, 56-60 and 69-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-11, 15-21, 56-60, 69 and 74-78 is/are rejected.
- 7) ☒ Claim(s) 70-73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/27/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 5/27/08 wherein claims 1, 11, 15-17, 19, and 69 were amended; claims 2, 3, 12-14, 22-55, and 61-68 were canceled; and claims 72-78 were added.

Note: Claims 1, 4-11, 15-21, 56-60, and 69-78 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 5/27/08 to the rejection of the claims made by the Examiner under 35 USC 103 have been fully considered and deemed persuasive for reasons of record (specifically, Applicant has amended the claims to overcome the rejections). Therefore, the said rejection is hereby withdrawn.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejections (Scope of Enablement)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 4-11, 15-21, 56-60, 69, and 74-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for amino-containing agents such as Tris, 2-amino-ethanol, aminosorbitol, and glucosamine, does not reasonably provide enablement for all amino-containing agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation wherein any amino-containing agents other than Tris, 2-aminoethanol, aminosorbitol, and glucosamine are utilized.

The disclosure of the present invention is directed to microsphere comprising crosslinked polyvinylalcohol having a diameter ranging from 10 micrometers to about 2,000 micrometers and having aldehydes on the microspheres that are neutralized by an amino-containing agent. While a skilled artisan would be motivated to select a amino-containing agents such as aminoalcohols (i.e., Tris, 2-aminoethanol, aminosorbitol, and glucosamine) which are capable of neutralizing aldehydes, the artisan would not know what other amino-containing agents Applicant is referring to which would be compatible with the instant invention. Hence, a skilled artisan in the art would not be able to readily ascertain the unlimited number of amino-containing agents derived or obtained from known and/or hypothetical substances and containing essential elements to obtain the results desired by Applicant. Thus, the skilled artisan

would be forced to randomly test various amino-containing agents in order to determine which agents possess chemical properties which would yield similar/same results as that obtained when using Tris, 2-aminoethanol, aminosorbitol, and glucosamine. Furthermore, the amount of guidance present in the specification fails to present the necessary instructions to determine what specific agents are encompassed by the claims. For example, aminoiminomethyl is an amino-containing agent. However, it is not known in the art for neutralizing aldehydes.

The specification does not provide guidance as to any specific substances other than the aminoalcohols Tris, 2-aminoethanol, aminosorbitol, and glucosamine which are used in the instant invention. In addition, the specification fails to provide guidance as to how one goes about selecting the specific amino-containing compounds of the instant invention to obtain the desired results for the microspheres. Hence, without such information, one skilled in the art could not predict which substances out of the vast number of known substances and hypothetical substances that are encompassed by Applicant's phrase "amino-containing agent". Therefore, due to the lack of guidance and the amount of experimentation required to identify the 'amino-containing agents' necessary for the instant invention, the instant invention is not properly enabled by the specification.

112 First Paragraph Rejections (Written Description)

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the

world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention. What the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Specifically, the instant invention is directed to microspheres having an amino-containing agent. An amino-containing agent is any compound/substance having an amino group. The phrase 'amino-containing agent' encompasses a multitude of possible agents that would not

necessarily include those listed by Applicant (Tris, 2-aminoethanol, aminosorbitol, and glucosamine). The only appearances of the phrase 'amino-containing agent' in the specification is on page 16, lines 3-31, and page 17, lines 27-31, which only disclose Tris, 2-aminoethanol, aminosorbitol, and glucosamine as the amino-containing agents. Thus, the specification does not sufficiently describe in detail any other amino-containing agents encompassed by the instant invention. Hence, the written description requirement is lacking in the instant invention since the term 'amino-containing agent' as set forth above is not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

112 Second Paragraph Rejections

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 4-11, 15-21, 56-60, 69, and 74-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because of the phrase 'amino-containing agent'. In particular, it is unclear what amino-containing agents Applicant is claiming that are compatible with the instant invention because not all amino-containing agents are capable of neutralizing the aldehyde groups on microspheres (e.g., aminoiminomethyl).

CLAIM OBJECTIONS

7. Claims 70-73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

COMMENTS/NOTES

8. It should be noted that no prior art has been cited against the instant invention. However, Applicant **MUST** address and overcome the 112 rejections above.

Specifically, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious aldehydes on the microspheres which are neutralized by amino-containing agents such as Tris, 2-aminoethanol, aminosorbitol, and glucosamine as disclosed in the specification.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

September 1, 2008